

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 102258.370WO1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/002257	International filing date (<i>day/month/year</i>) 24 January 2005 (24.01.2005)	Priority date (<i>day/month/year</i>) 22 January 2004 (22.01.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NITROMED, INC.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 6 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 24 July 2006 (24.07.2006)</p> <p>Authorized officer Dorothee Mülhausen</p> <p>e-mail: pt01@wipo.int</p>
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PATENT COOPERATION TREATY

REC'D 03 AUG 2005

WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: EDWARD D. GRIEFF WILMER, CUTLER PICKERING HALE AND DORR LLP 1455 PENNSYLVANIA AVENUE, NW WASHINGTON, DC 20004			Date of mailing <i>(day/month/year)</i> 01 AUG 2005
Applicant's or agent's file reference 102258.370WO1		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US05/02257	International filing date <i>(day/month/year)</i> 24 January 2005 (24.01.2005)	Priority date <i>(day/month/year)</i> 22 January 2004 (22.01.2004)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/04 and US Cl.: 514/579			
Applicant NITROMED, INC.			

1. This opinion contains indications relating to the following items:

- ☒ **Box No. I** Basis of the opinion
- ☐ **Box No. II** Priority
- ☒ **Box No. III** Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ **Box No. IV** Lack of unity of invention
- ☒ **Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ **Box No. VI** Certain documents cited
- ☒ **Box No. VII** Certain defects in the international application
- ☐ **Box No. VIII** Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer James Q. Wilson Telephone No. (703) 308-1235
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/02257

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language ____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/02257

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. Claim 4 is missing and therefore cannot be examined.

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 4 is missing and it is unknown as to what the claim is directed to.

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for said claims Nos. _____
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | | |
|----------------------------|--------------------------|-----------------------------------|
| the written form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02257

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>9-15</u>	YES
	Claims <u>1-3, 5-8 and 16-18</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-3 and 5-18</u>	NO
Industrial applicability (IA)	Claims <u>1-3 and 5-18</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 5-8 and 16-18 lack novelty under PCT Article 33(2) as being anticipated by Bolla et al. and Garvey. Bolla et al. (see entire document and paragraph 232) and Garvey (see entire document and in particular claims 1-8) teach the claimed compounds and compositions.

Claims 1-3 and 5-18 lack an inventive step under PCT Article 33(3) as being obvious over Garvey and Bolla et al. in view of Letts et al., Garvey et al. and Earl et al. Garvey (see citation above) and Bolla et al. (see citation above) teach those compounds, compositions and similar methods claimed by the applicant and Letts et al. (see entire document and in particular paragraph 232), Garvey et al. (see entire document) and Earl et al. (see entire document and in particular paragraphs 353 and 356). Garvey and Bolla et al. teach similar compounds, compositions and methods of using nitrosylated and nitrosated compounds.

Claims 1-3 and 5-18 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/02257

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 4 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Claim 4 is missing.

PATENT COOPERATION TREATY

REC'D 03 AUG 2005
 WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
EDWARD D. GRIEFF
WILMER, CUTLER PICKERING HALE AND DORR LLP
1455 PENNSYLVANIA AVENUE, NW
WASHINGTON, DC 20004

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer James O. Wilson Telephone No. (703) 308-1235
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Form PCT/ISA/237 (cover sheet) (January 2004)

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INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/02257

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| | <input type="checkbox"/> | does not comply with the standard |
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- ☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/02257

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>9-15</u>	YES
	Claims <u>1-3, 5-8 and 16-18</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-3 and 5-18</u>	NO
Industrial applicability (IA)	Claims <u>1-3 and 5-18</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

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